

CLAIMS

1. A DNA vaccine composition comprising a recombinant construct comprising an isolated nucleic acid sequence encoding an antigen selected from CD25, homologs and fragments thereof; the nucleic acid sequence being operably linked to one or more transcription control sequences; and a pharmaceutically acceptable carrier, adjuvant, excipient or diluent.
2. The composition of claim 1, wherein the CD25 is human CD25.
3. The composition of claim 1, wherein the isolated nucleic acid sequence has a nucleic acid sequence as set forth in SEQ ID NO:1.
4. The composition of claim 1, wherein the isolated nucleic acid sequence encodes an antigen having an amino acid sequence as set forth in any one of SEQ ID NOS:2-4.
5. The composition of claim 1, wherein the composition is a naked DNA vaccine.
6. The composition of claim 1, wherein said carrier is selected from the group consisting of liposomes, micelles, emulsions and cells.
7. The composition of claim 1, wherein said transcription control sequences are selected from the group consisting of: RSV control sequences, CMV control sequences, retroviral LTR sequences, SV-40 control sequences and β -actin control sequences.
8. The composition of claim 1, wherein said recombinant construct is a eukaryotic expression vector.
9. The composition of claim 8, wherein said eukaryotic expression vector is selected from the group consisting of: pcDNA3, pcDNA3.1(+/-), pZeoSV2(+/-), pSecTag2, pDisplay, pEF/myc/cyto, pCMV/myc/cyto, pCR3.1, pCI, pBK-RSV, pBK-CMV and pTRES.
10. A method of preventing or inhibiting the development of a T-cell mediated pathology, comprising administering to a subject in need thereof a therapeutically effective amount of a pharmaceutical composition comprising: (a) a recombinant construct, said recombinant construct comprising an isolated nucleic acid sequence encoding an antigen selected from: CD25, homologs and fragments thereof, wherein the nucleic acid sequence is operably linked to one or more transcription control sequences; and (b) a pharmaceutically acceptable carrier, excipient or diluent.

11. The method of claim 10, wherein the CD25 is human CD25.
12. The method of claim 10, wherein the isolated nucleic acid sequence is as set forth in SEQ ID NO:1.
13. The method of claim 10, wherein the isolated nucleic acid sequence encodes an antigen having an amino acid sequence as set forth in any one of SEQ ID NOS:2-4.
14. The method of claim 10, wherein said T cell-mediated pathology is an autoimmune disease.
15. The method of claim 14, wherein said T cell-mediated autoimmune disease is selected from the group consisting of: multiple sclerosis, rheumatoid arthritis, autoimmune neuritis, systemic lupus erythematosus, psoriasis, Type I diabetes mellitus, Sjogren's disease, thyroid disease and myasthenia gravis.
16. The method of claim 10, wherein said T cell-mediated pathology is graft rejection.
17. The method of claim 10, wherein said T cell-mediated pathology is a Th1-mediated inflammatory disease.
18. The method of claim 10, wherein the antigen is expressed in sufficient amount and duration to increase anti-ergotypic T cell response in said subject, thereby inhibiting or preventing the development of said T-cell mediated pathology.
19. The method of claim 18, wherein said increase in anti-ergotypic T cell response is characterized by a reduction in the secretion of IFN γ and an increase in the secretion of IL-10.
20. The method of claim 10, wherein the nucleic acid composition is administered as naked DNA.
21. The method of claim 10, wherein said subject is human.
22. A method for preventing or inhibiting the development of a T-cell mediated pathology comprising the steps of (a) obtaining cells from a subject; (b) transfecting the cells *in vitro* with a recombinant construct comprising an isolated nucleic acid sequence encoding an antigen selected from: CD25, homologs and fragments thereof, the nucleic acid sequence being operably linked to one or more transcription control sequences; and (c) reintroducing a therapeutically effective number of the transfected cells to the

subject, thereby preventing or inhibiting the development of the T-cell mediated pathology.

23. The method of claim 22, wherein the CD25 is human CD25.

24. The method of claim 22, wherein the isolated nucleic acid sequence is as set forth in SEQ ID NO:1.

25. The method of claim 22, wherein the isolated nucleic acid sequence encodes an antigen having an amino acid sequence as set forth in any one of SEQ ID NOS:2-4.

26. The method of claim 22, wherein said T cell-mediated pathology is an autoimmune disease.

27. The method of claim 26, wherein said T cell-mediated autoimmune disease is selected from the group consisting of: multiple sclerosis, rheumatoid arthritis, autoimmune neuritis, systemic lupus erythematosus, psoriasis, Type I diabetes mellitus, Sjogren's disease, thyroid disease and myasthenia gravis.

28. The method of claim 22, wherein said T cell-mediated pathology is graft rejection.

29. The method of claim 22, wherein said T cell-mediated pathology is a Th1-mediated inflammatory disease.

30. The method of claim 22, wherein the antigen is expressed in sufficient amount and duration to increase anti-ergotypic T cell response in said subject, thereby inhibiting or preventing the development of said T-cell mediated pathology.

31. The method of claim 30, wherein said increase in anti-ergotypic T cell response is characterized by a reduction in the secretion of IFN γ and an increase in the secretion of IL-10.

32. The method of claim 22, wherein said subject is human.

33. Use for the preparation of a DNA vaccine of a recombinant construct comprising an isolated nucleic acid sequence encoding an antigen selected from: CD25, homologs and fragments thereof, the nucleic acid sequence being operably linked to one or more transcription control sequences; for preventing or inhibiting the development of a T-cell mediated pathology.

34. The use of claim 33, wherein the composition is as set forth in any one of claims 1-9.

35. The use of claim 33, wherein said T cell-mediated pathology is an autoimmune disease.

5 36. The use of claim 35, wherein said T cell-mediated autoimmune disease is selected from the group consisting of: multiple sclerosis, rheumatoid arthritis, autoimmune neuritis, systemic lupus erythematosus, psoriasis, Type I diabetes mellitus, Sjogren's disease, thyroid disease and myasthenia gravis.

37. The use of claim 33, wherein said T cell-mediated pathology is graft rejection.

10 38. The use of claim 33, wherein said T cell-mediated pathology is a Th1-mediated inflammatory disease.

39. The use of claim 33, wherein the antigen is expressed in sufficient amount and duration to increase an anti-ergotypic T cell response, to prevent or inhibit the development of said T-cell mediated pathology.

15 40. The use of claim 39, wherein said increased anti-ergotypic T cell response is characterized by a reduction in the secretion of IFN γ and an increase in the secretion of IL-10.

41. Use for the preparation of a medicament of a recombinant construct comprising an isolated nucleic acid sequence encoding an antigen selected from: CD25, homologs
20 and fragments thereof, the nucleic acid sequence being operably linked to one or more transcription control sequences; for transforming, transfecting or infecting cells ex vivo for preventing or inhibiting the development of a T-cell mediated pathology.

42. The use of claim 41, wherein the composition is as set forth in any one of claims 1-9.

25 43. The use of claim 41, wherein said T cell-mediated pathology is an autoimmune disease.

44. The use of claim 43, wherein said T cell-mediated autoimmune disease is selected from the group consisting of: multiple sclerosis, rheumatoid arthritis, autoimmune neuritis, systemic lupus erythematosus, psoriasis, Type I diabetes mellitus,
30 Sjogren's disease, thyroid disease and myasthenia gravis.

45. The use of claim 41, wherein said T cell-mediated pathology is graft rejection.

46. The use of claim 41, wherein said T cell-mediated pathology is a Th1-mediated inflammatory disease.

47. The use of claim 41, wherein the antigen is expressed in sufficient amount and
5 duration to increase an anti-ergotypic T cell response, to prevent or inhibit the development of said T-cell mediated pathology.

48. The use of claim 47, wherein said increased anti-ergotypic T cell response is characterized by a reduction in the secretion of IFN γ and an increase in the secretion of IL-10.